MAY 1 4 2002

**EXHIBIT 2**

K013840

**CANÈ S.r.l.**
**Via Pavia, 105/I 10090**
**Rivoli-Cascine Vica (Torino) Italy**
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**Contact: Mario Cané, President**
**January 30, 2002**

## 510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   **Proprietary-Trade Name:** "Microjet *Crono K" and "Crono go"*
   **Classification Name:** 80 FRN
   **Common/Usual Name:** Ambulatory Infusion Pump

2. **Equivalent legally marketed devices** This product is similar in function to the Cadd-Legacy 1 Ambulatory Infusion Pump , Sims Deltec, Inc., K982838

3. **Indications for Use (intended use)** The portable Microjet Crono K infusion device has been designed only for use in subcutaneous and intravenous infusion of prescribed liquid medicines.

4. **Description of the Device**: Canè s.r.l., a company that specializes in the production of ambulatory pumps, has now produced a new generation of compact pumps: Crono K, a perfect combination of high technology and innovative design. The infusion pumps which use normal commercial syringes are inevitably cumbersome and thus difficult to use in everyday life. This provokes in the patients a refuse of the therapy. A special syringe, an integral part of the Crono K allows an efficient reduction of the pump size. In this way, the patients can freely carry out the therapy at any time of the day, even during their everyday life. Patients who have been following a iron chelation therapy for a long time, often experience difficulties in absorbing the drug subcutaneously; this may lead to a catheter occlusion with consequent interruption of the infusion. Crono K has a particular mechanism which pushes directly the rubber syringe piston: so it is possible to reach a thrust force up to 3 times higher with respect to conventional pumps. In case of catheter occlusion, an innovative infusion control system makes it possible to proceed with the infusion automatically and, after the occlusion is eliminated, to complete it. For a better absorption of the drug, Crono K makes the infusion up to 3 times more fractionated with respect to traditional pumps (22 ml per impulse, using a 10/20 ml syringe). Crono K is fitted with a liquid crystal display which shows the time it takes to complete the delivery and battery charge status.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, EMC, and user testing indicates that the new device is as safe and effective as the predicate device.

## 6. Substantial Equivalence Chart

| **Characteristic** | **Cadd-Legacy 1 Ambulatory Infusion Pump , Sims Deltec, Inc., K982838** | **"Microjet *Crono K*" and "Crono go" K013840** |
|---|---|---|
| Intended Use: | Intravenous<br>Intra-arterial<br>Subcutaneous<br>Intraperitoneal<br>Epidural<br>Intrathecal | Subcutaneous and intravenous only |
| Physical characteristics: | | |
| Power Source | 2 AA alkaline batteries, AC Adapter | Lithium battery (3V) of the CR-123 A type |
| Size | 4.4 x 3.8 x 1.6 x in (112x 95x41 mm) | 3" x 1.85" x 1.14" (77 x 47 x 29 mm) |
| Weight | 13.8 oz (392 grams) | 4.0 oz (115 g) (battery included). |
| Capacity | 10 ml | 10 or 20 ml |
| Warranty: | 1 year | 2 years |

## 7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of CANÈ S.r.l. that the Microjet Crono K is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2002

Cane S. R. L
C/O Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K013840
Trade/Device Name: MicroJet Crono K and Crono GO
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: February 26, 2002
Received: February 28, 2002

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**j) Indications for Use**

**510(k) Number K013840**

**Device Name: "Microjet *Crono K"* and "Crono go" ambulatory infusion pump**

**Indications for Use:** The "**Microjet *Crono K"* and "Crono go" ambulatory infusion pump** device has been designed for use in subcutaneous and intravenous infusion of prescribed liquid medicines.

_____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013840